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09/560,046	04/27/2000	David C. Greenspan	028870-224	2871

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EXAMINER
PAK, JOHN D

ART UNIT	PAPER NUMBER
1616	17

DATE MAILED: 06/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/560,046	Greenspan et al.
Examiner	**Art Unit**
John Pak	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 6, 2003*

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-12 and 15-37* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5) ☒ Claim(s) *18, 19, 21, and 22* is/are allowed.

6) ☒ Claim(s) *1-12, 15, 16, 20, 23, 24, 26, 29, and 32-37* is/are rejected.

7) ☒ Claim(s) *17, 25, 27, 28, 30, and 31* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examine

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 1-12 and 15-37 are pending in this application.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 7-11, 32-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,338,751. Although the conflicting claims are not identical, they are not patentably distinct from each other because the bioactive particles claimed in the patent would necessarily have the properties claimed in the instant application claims due to the fact that they are made of the same

components. A carrier is included or encompassed by the patented claims because the patented claims are recited in terms of "comprising." While it is recognized that the patented claims refer to a dental use, it is the composition per se that is being examined, not its use. The composition per se in the patented claims recites bioactive glass that the instant application claims encompass. SEM or laser light scattering techniques for measuring particle size in applicant's dependent claims are noted, but since the patented claims already require the same sizes as applicant's claims, such measuring techniques do not affect the composition that is claimed. Therefore, one of ordinary skill in the art would have recognized above noted claims of the instant application as being an obvious variant of claims 1-2 of the patented claims.

Applicant's remarks in the reply of 2/6/03 regarding the 6,338,751 patent have been given due consideration but they were deemed unpersuasive.

Applicant argues that the patented claims do not describe or suggest a composition for the accelerated healing of wounds and burns and/or for improving the appearance of scar tissue resulting from such wounds and burns. The Examiner maintains that applicant's claims are directed to compositions, not methods. Compositions of application claims 1 and 7-11 are recited in an amount effective to deliver such wound/burn/scar tissue effects, and compositions of application claims 32-37 are recited in an amount effective to deliver antibacterial effect. But how could there be any distinguishing feature in such language? What do those "effective" amounts mean? Do they mean an amount that is not covered by the amount that's covered in the patented claims? That seems not possible since the patented claims are readable on amounts of

bioactive glass both large and small – it is presumed that the patented claims cover, for example, 0.1 g of a bioactive glass composition as well as 10 g of bioactive glass composition. It is the Examiner's position that the amounts of bioactive glass encompassed by the compositions of the patented claims are sufficient to possess the properties now claimed by applicant in the instant claims. There are not many specific "effective amount" disclosures in applicant's application in terms of actual concentration or weight amounts, but see for example specification Example 3 on pages 25-26, wherein 5 g of particulate bioactive glass is used. The Examiner maintains that the "effective amount" language in the application claims is simply a matter of how much (e.g. 0.5 g, 5 g, 10 g, etc.) bioactive glass is present, and such amounts of bioactive glass are clearly encompassed by the patented claims.

Applicant further argues that the patented claims do not describe or suggest a composition comprising non-linked, small particles of bioactive glass for the same use as noted above. This argument has no merit. According to applicant's definition of "non-linked," it means glass that is "in the form of small, discrete particles, rather than a fused matrix of particles or a mesh or fabric of glass fibers." (specification p. 7, lines 27-28). The patented claims are directed to particulate bioactive glass, including particles less than about 90 μm and 2 μm. Nothing is mentioned about matrix, mesh, or any other reference to a fused form. In such absence of contrary indication, the term "particulate" indicates and encompasses non-linked form.

Similar arguments are made with respect to claim 32 and its dependent claim(s), but for the reasons stated above, the patented claims encompass bioactive particles that would have the properties recited in claim 32 and its dependents.

Claim 23 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,972,384. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Patented claim 1 is directed to a particulate ceramic-glass matrix impregnated with microencapsulated drugs. Patented claim 6 is directed to a composition comprising bioactive glass and drugs encapsulated with non-ceramic coatings which dissolve or degrades in a physiological environment. Patented claim 7 is directed to a controlled release pharmaceutical formulation comprising *particles* of bioactive glass and particles of microencapsulated drugs.

Instant application claim 23 is directed to a composition wound/burn/scar utility comprising non-linked, small particles of bioactive glass in a carrier combined with a biocompatible, biodegradable material to form a composite material.

* Utility: as discussed in the previous ground of rejection, the utility in the application claim must be present in the patented claim because both compositions contain the same exact bioactive glass. "Effective amount" claim language does not distinguish the compositions, as explained earlier in this Office Action, because such feature is merely a matter of how much

bioactive glass is present, and the patented compositions clearly reads on the ordinary amounts (e.g., 0.5 g, 5 g, 10 g) of bioactive glass.

* Non-linked, small particles of bioactive glass: it must be noted that application claim 23 is written so that non-linked glass is used to form a "composite material." Hence, the claim is open to a final composition that is not in non-linked form. The patented claims clearly disclose such compositions. The bioactive glass of the patented claims are initially non-linked. Nothing is mentioned about matrix, mesh, or any other reference to a fused form with respect to the bioactive glass that is initially used. In such absence of contrary indication, the term "particles" indicates and encompasses non-linked form. The "small particles" feature is clearly suggested since "particles" in a "controlled release" formulation context and "particulate" context suggest that the glass particles are small.

* Carrier combined with a biocompatible, biodegradable material to form a composite material: Patented claim 6 clearly discloses bioactive glass and microencapsulated drugs wherein the encapsulation is with a non-ceramic coating material which dissolves or degrades in a physiological environment. Patented claim 7 is directed to a controlled release formulation. Clearly such claim features explicitly specify and match the carrier and biocompatible/ biodegradable material features of the application claims.

Applicant's arguments of 2/6/03 with respect to the 5,972,384 patent have been considered, but found unpersuasive. All of applicant's arguments have been addressed above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 6, 7-11, 23, 32-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Litkowski (US 6,338,751).

As discussed above, Litkowski specifically teaches the same bioactive glass particles-containing compositions, albeit for a different utility. See claims 1-2, column 7, lines 29-46 (addition of F^-, particle size less than 2 μm, and gel formulation are disclosed), and Example 1 on column 8. The invention being examined here is directed to the composition per se, not methods.

With respect to claim 23, which has not been previously discussed vis-a-vis Litkowski, it is noted that the gel formulation disclosed by Litkowski meets the "biocompatible, biodegradable material to form a composite composition" feature.

Applicant argues that the patented claims do not describe or suggest a composition for the accelerated healing of wounds and burns and/or for improving the appearance of scar tissue resulting from such wounds and burns. However, applicant's claims are directed to compositions, not methods. Compositions of application claim 1, its dependents, and claim 23 are recited in an amount effective to deliver such wound/burn/scar tissue effects, and compositions of application claims 32-37 are recited in an amount effective to deliver antibacterial effect. But how could there be any distinguishing feature in such language? What do those "effective" amounts mean? Do they mean an amount that is not covered by the amount in the patented claims? That seems not possible since the patented claims are readable on amounts of bioactive glass both large and small – it is presumed that the patented claims cover, for example, 0.1 g of a bioactive glass composition as well as 10 g of bioactive glass composition. Such amounts are reasonable amounts to prepare "dentin tubule occluding

amount." It is the Examiner's position that the amounts of bioactive glass encompassed by the compositions of the patented claims are sufficient to possess the properties now claimed by applicant in the instant claims. There are not many specific "effective amount" disclosures in applicant's application in terms of actual concentration or weight amounts, but see for example specification Example 3 on pages 25-26, wherein 5 g of particulate bioactive glass is used. The Examiner maintains that the "effective amount" language in the application claims is simply a matter of how much (e.g. 0.5 g, 5 g, 10 g, etc.) bioactive glass is present, and such amounts of bioactive glass are clearly encompassed by the patented claims.

Applicant has argued in the reply of 2/6/03 that the patented claims do not describe or suggest a composition comprising non-linked, small particles of bioactive glass for the same use as noted above. This argument has no merit. According to applicant's definition of "non-linked," it means glass that is "in the form of small, discrete particles, rather than a fused matrix of particles or a mesh or fabric of glass fibers." (specification p. 7, lines 27-28). The patented claims are directed to particulate bioactive glass, including particles less than about 90 μm and 2 μm. Nothing is mentioned about matrix, mesh, or any other reference to a fused form. In such absence of contrary indication, the term "particulate" indicates and encompasses non-linked form.

Claims 1, 7, 8, 32-34 stand rejected under 35 U.S.C. 102(e) as being anticipated by Hench et al. (US 5,840,290) for the reasons of record – see Paper No. 15, pages 8-9 regarding the reasons for the section 102 ground.

Applicant's arguments relative hereto have been given due consideration but they were deemed unpersuasive. Again, applicant makes the same argument that the disclosed compositions, which contain the same exact bioactive glass, do not have a description or suggestion of applicant's burn/wound/scar tissue utility. Applicant argues that the cited patent does not describe or suggest a composition for the accelerated healing of wounds and burns and/or for improving the appearance of scar tissue resulting from such wounds and burns. However, applicant's claims are directed to compositions, not methods. Compositions of application claim 1 and its dependents are recited in an amount effective to deliver such wound/burn/scar tissue effects, and compositions of application claims 32-34 are recited in an amount effective to deliver antibacterial effect. But how could there be any distinguishing feature in such language? What do those "effective" amounts mean? Do they mean an amount that is not covered by the amount in the patented claims and disclosure? That seems not possible since the reference claims are readable on amounts of bioactive glass both large and small – it is presumed that the patented claims cover, for example, 0.1 g of a bioactive glass composition as well as 10 g of bioactive glass composition. See also Example 1 on column 5, where 5.0 cc Bioglass 45S5 is used. Such amounts are reasonable amounts for possessing the properties claimed by applicant. It is the Examiner's position that the amounts of bioactive glass

encompassed by the compositions of the patented disclosure are sufficient to possess the properties now claimed by applicant in the instant claims. There are not many specific "effective amount" disclosures in applicant's application in terms of actual concentration or weight amounts, but see for example specification Example 3 on pages 25-26, wherein 5 g of particulate bioactive glass is used. The Examiner maintains that the "effective amount" language in the application claims is simply a matter of how much (e.g. 0.5 g, 5 g, 5 cc, 10 g, etc.) bioactive glass is present, and such amounts of bioactive glass are clearly encompassed by the patented claims.

Applicant has argued in the reply of 2/6/03 that the cited reference does not describe or suggest a composition comprising non-linked, small particles of bioactive glass for the same use as noted above. This argument has no merit. According to applicant's definition of "non-linked," it means glass that is "in the form of small, discrete particles, rather than a fused matrix of particles or a mesh or fabric of glass fibers." (specification p. 7, lines 27-28). The patented claims are directed to particulate bio-compatible glass, including particles 90 μm to 250 μm. Nothing is mentioned about matrix, mesh, or any other reference to a fused form. In such absence of contrary indication, the term "particulate" indicates and encompasses non-linked form and small particles.

Claims 1, 7, 8 and 32-34 stand rejected under 35 U.S.C. 102(b) as being anticipated by Low et al. (US 4,851,046) for the reasons of record – see Paper No. 15, page 9 regarding the reasons for the section 102 ground.

Applicant's arguments relative hereto have been given due consideration but they were deemed unpersuasive. Again, applicant makes the same argument that the disclosed compositions, which contain the same exact bioactive glass, do not have a description or suggestion of applicant's burn/wound/scar tissue utility. Applicant argues that the cited patent does not describe or suggest a composition for the accelerated healing of wounds and burns and/or for improving the appearance of scar tissue resulting from such wounds and burns. However, applicant's claims are directed to compositions, not methods. Compositions of application claim 1 and its dependents are recited in an amount effective to deliver such wound/burn/scar tissue effects, and compositions of application claims 32-34 are recited in an amount effective to deliver antibacterial effect. But how could there be any distinguishing feature in such language? What do those "effective" amounts mean? Do they mean an amount that is not covered by the amount in the patented claims and disclosure? That seems not possible since the reference claims and disclosure disclose amounts of bioactive glass both large and small – it is presumed that the patented claims cover, for example, 0.1 g of a bioactive glass composition as well as 10 g of bioactive glass composition. Such amounts are reasonable amounts for possessing the properties claimed by applicant. It is the Examiner's position that the amounts of bioactive glass encompassed by the compositions of the patented disclosure are sufficient to possess the properties now claimed by applicant in the instant claims. There are not many specific "effective amount" disclosures in applicant's application in terms of actual concentration or weight amounts, but see for example specification Example 3 on pages 25-26,

wherein 5 g of particulate bioactive glass is used. The Examiner maintains that the "effective amount" language in the application claims is simply a matter of how much (e.g. 0.5 g, 5 g, 5 cc, 10 g, etc.) bioactive glass is present, and such amounts of bioactive glass are clearly encompassed by the patented claims.

Applicant has argued in the reply of 2/6/03 that the cited reference does not describe or suggest a composition comprising non-linked, small particles of bioactive glass for the same use as noted above. This argument has no merit. According to applicant's definition of "non-linked," it means glass that is "in the form of small, discrete particles, rather than a fused matrix of particles or a mesh or fabric of glass fibers." (specification p. 7, lines 27-28). The patented claims are directed to particulate bio-compatible glass, including particles 90 μm to 350 μm (see claim 4). Nothing is mentioned about matrix, mesh, or any other reference to a fused form. In such absence of contrary indication, the term "particulate" indicates and encompasses non-linked form and small particles.

Claims 1-3, 12, 20, 23, 24, 26, 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Medline abstract 89036678.

Medline abstract 89036678 discloses hydroxyapatite particles or hydroxyapatite particles/collagen complex for applying to periodontal wounds. Improved wound healing is reported.

Claims 1-3: requires non-linked, small particles of bioactive glass. The cited reference discloses particles of hydroxyapatite, which is defined by applicant as a suitable bioactive glass. See specification page 7, line 24. The "small" feature is met since the particles used in the reference could not have been large due to their application to periodontal defects. The "non-linked" feature is met because the particles are not disclosed to be in a fused matrix, mesh or fabric (see previous discussions of this feature). The claims also require accelerated wound healing amount. This feature is clearly met as the hydroxyapatite applied subjects exhibited improved healing: larger amount of new cementum formation and stronger interdigitation between the root surface and the gingival connective tissue fibers. As the control subjects did not exhibit such improvements, accelerated healing was obtained. Therapeutic agent required in claims 1-3 is met by the disclosed collagen complex. Carrier is met by the conventional carrier that would have been present for a collagen-containing complex. The claims are anticipated.

Claim 12 and 20: see above discussion in the immediately preceding paragraph. Same rationale apply.

Claim 23: the composition is combined with a biocompatible, biodegradable material to form a composite material. First, the same rationale as claims 1-3 apply here as well. Second, the biocompatible, biodegradable material is met by the collagen material that is used to form the complex in the cited reference. The composite material is met by the hydroxyapatite-collagen complex.

Claims 24 and 26: claim 24 is directed to reducing the level of inflammation in a wound and claim 26 is directed to reducing the level of bacterial infection in a wound. It is recognized that the cited reference does not explicitly disclose inflammation or bacterial infection. However, inflammation and bacterial presence cannot be avoided in a wound. Therefore, since the same exact hydroxyapatite has been administered to the same site (wound), taken with the disclosure that substantial healing improvements were obtained, it is the Examiner's position that the disclosed amounts needed to implant hydroxyapatite into periodontal osseous defects are sufficient to also deliver reduced inflammation and reduced bacterial infection. The claims are thereby anticipated.

Claim 32: requires an antibacterially effective amount of non-linked, small particles of bioactive glass. Only the antibacterial amount has not been discussed already. For the other features, the rationale set forth with respect to claims 1-3 is incorporated herein by reference. As for the antibacterial effect, since the same exact hydroxyapatite has been administered to the same site (wound), taken with the reference disclosure that substantial healing improvements were obtained, it is the Examiner's position that the disclosed amounts needed to implant hydroxyapatite into periodontal osseous defects are sufficient to also deliver antibacterial effect.

The claims are thereby anticipated.

Claims 1-4, 12, 20, 23, 24, 26, 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Medline abstract 85209111.

Medline abstract 85209111 explicitly discloses hydroxyapatite granules that contain an antibiotic such as flucloxacillin. Dogs with staphylococcal osteomyelitis were treated with the hydroxyapatite granules after wound closure. Treatment is disclosed to be effective.

Claims 1-4: requires non-linked, small particles of bioactive glass. The cited reference discloses granules of hydroxyapatite, which is defined by applicant as a suitable bioactive glass. See specification page 7, line 24. The "small" feature is met since the granules used in the reference could not have been large due to the fact that granules are small to begin with and their application in the local treatment of osteomyelitis would necessitate smaller granules so that they are not "large." The "non-linked" feature is met because the granules are not disclosed to be in a fused matrix, mesh or fabric (see previous discussions of this feature). The claims also require accelerated wound healing amount. This feature is clearly met as the hydroxyapatite applied subjects were effectively treated. Accelerated healing must necessarily be obtained when staphylococcal osteomyelitis is treated with an antibiotic such as flucloxacillin. Carrier is met by the conventional carrier that would have been present for a granule. The claims are anticipated.

Claim 12 and 20: see above discussion in the immediately preceding paragraph. Same rationale apply.

Claim 23: the composition is combined with a biocompatible, biodegradable material to form a composite material. First, the same rationale as claims 1-3 apply here as well. Second,

the biocompatible, biodegradable material is met by the granule material. The composite material is met by the hydroxyapatite-flucloxacillin granule.

Claims 24 and 26: claim 24 is directed to reducing the level of inflammation in a wound and claim 26 is directed to reducing the level of bacterial infection in a wound. Both therapeutic effects are explicitly disclosed because, by definition, an effective treatment of staphylococcal osteomyelitis is an effective reduction of level of inflammation and bacterial infection in a wound.

Claim 32: requires an antibacterially effective amount of non-linked, small particles of bioactive glass. The bioactive glass-containing hydroxyapatite-flucloxacillin has been disclosed as being effective for treating staphylococcal osteomyelitis. Therefore, the bioactive hydroxyapatite was present in an amount effective to be antibacterially effective.

The claims are thereby anticipated.

Claims 1-5, 9, 12, 20, 23, 24, 26, 29, 32, 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Nikolaychik et al. (US 5,702,715).

Nikolaychik et al. explicitly disclose reinforced biological sealants that contain bioactive glass. See the paragraph bridging columns 6 and 7 & Example 4 on columns 11-12. Topical delivery to wounds, surgically open surfaces, and sutures is disclosed (column 1, lines 4-7; see also column 3, lines 24-39, column 4, lines 39-40 & 52-56, column 6, lines 62-67). Table 13 on column 12 discloses 80 μm hydroxyapatite granules at a concentration of 3 g/l, in combination

with various other therapeutic agents and carriers. Antibiotics such as erythromycin and tetracycline are specifically exemplified (column 7, Table 4; see also column 11, lines 48-54).

The claims are thereby anticipated. In re Sivaramakrishnan, 213 USPQ 41 (CCPA 1982). Non-linked, small particles are disclosed because nothing is said about a fused glass or glass in a matrix. In the absence of such contrary disclosure, the disclosed small particle size of 80 μm meets the non-linked, small particle size requirement. Wound treatment is explicitly disclosed. Accelerated healing, reduced level of inflammation, reduced level of bacterial infection, and antimicrobial effect would necessarily have been obtained with the wound treating compositions that are explicitly disclosed by the cited reference, because the same bioactive glass is used in the same site, wound. The same effect must necessarily be obtained. Effective amount languages are noted, but the reference discloses 2-50 wt% material such as glass ceramics, to be used as bone and teeth substitutes (column 6, lines 62-67). By any definition of "bioactive glass," such glass ceramics meets its requirements, particularly when specifically disclosed size of 80 μm is taken into account. It is the Examiner's position that applicant's compositions and method read on 2-50 wt% bioactive glass.

Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 8-126659.

JP 8-126659 discloses a medical base material that is to be used for wound-covering. The base material contains (a) a polyester support, which contains metalated-hydroxyapatite, metal

being known antimicrobial metals such as silver, copper or zinc, and (b) an adhesive agent. The wound covering material comprises the (i) base material, and (ii) a hydrophilic film laminated on the material. See English abstract - Derwent Abstract 1996-294740.

Claims 15-16 are directly readable on the disclosed wound-covering material. Wound covering material is equivalent to "wound dressing." A "bandage" is broad enough to read on the adhesive agent (b) in the base material or the combination of (i) and (ii), supra. Topical antibiotic is met by the silver, copper or zinc. Non-linked particles of bioactive glass is suggested by the hydroxyapatite. Hydroxyapatite, without more, conveys a solid substance that is not fused. The fact that the hydroxyapatite is supporting antibiotic metals is suggestive of particulate form because the particulate form is only one of several forms that is available to deliver the metalated-hydroxyapatite. Hydroxyapatites are typically available in particulate form; and as such, use of such particulate forms would have facilitated uniform incorporation into the polyester support.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly suggested by the teachings of the cited reference.

Applicant is apprised of claim 27 of U.S. Patent No. 5,977,204. Applicant's earliest priority date predates the filing date of the application that issued as this patent, so the patent cannot be cited as prior art.

Claims 18-19 and 21-22 are allowed.

Claims 17, 25, 27, 28, 30 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Previous indication of allowability of claim 23 had to be rescinded, because it was recognized during the review for this Office Action that several references explicitly anticipate the invention of claim 23.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Friday from 7:30 AM to 4 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

JOHN PAK
PRIMARY EXAMINER
GROUP 1600